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| APPLICATION NO. | FI | LING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|--|------------|------------|----------------------|---------------------|-----------------|
| 10/051,843 | 01/17/2002 | | Kathleen H. Young | AHP 98133 P1 | 3063 |
| 25291 | 7590 | 02/24/2004 | | EXAM | INER |
| WYETH | | | | MURPHY, JOSEPH F | |
| PATENT LAW GROUP FIVE GIRALDA FARMS | | | ART UNIT | PAPER NUMBER | |
| MADISON, | | | 1646 | | |

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|---|---|--|--|--|--|--|
| | 10/051,843 | YOUNG ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Joseph F Murphy | 1646 | | | | |
| The MAILING DATE of this communication ap | opears on the cover sheet wit | h the correspondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a replif NO period for reply sepecified above, the maximum statutory period. - Failure to reply within the set or extended period for reply will, by status Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | 136(a). In no event, however, may a re ply within the statutory minimum of thirty d will apply and will expire SIX (6) MONT te, cause the application to become ABA | ply be timely filed (30) days will be considered timely. HS from the mailing date of this communication. NDONED (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on 17. | Januarv 2002. | | | | | |
| | · · · · · · · · · · · · · · · · · · · | | | | | |
| | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) 1-44 is/are pending in the application 4a) Of the above claim(s) is/are withdra 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 1-44 are subject to restriction and/or | awn from consideration. | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| i-i-)[i-ne-oatn-or-declaration-is-objected-to-by-the-E | :xaminerNote-the-attached | Oπice-Action-or-form-PTO-152. | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority document * See the attached detailed Office action for a list | nts have been received. Its have been received in Appority documents have been reau (PCT Rule 17.2(a)). | plication No eceived in this National Stage | | | | |
| Attachment(s) | Λ□ uu · · · | | | | | |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08 Paper No(s)/Mail Date | Paper No(s) | mmary (PTO-413) /Mail Date ormal Patent Application (PTO-152) - | | | | |

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, 28 drawn to a method for identification of a compound which inhibits binding of an intracellular receptor region of an alpha-subunit of a voltage gated ion channel and an amino terminal inactivation region of an ion channel protein, classified in class 435, subclass 7.2.
- II. Claims 11-27, drawn to a host cell comprising a first hybrid protein comprising a DNA binding domain and a second protein comprising an activation domain, classified in class 435, subclass 325.
- III. Claims 29-38, drawn to a host cell comprising a first hybrid protein comprising an intracellular region of a voltage gated ion channel and a second protein comprising an amino terminal inactivation region of an ion channel protein, classified in class 435, subclass 325.
- IV. Claims 39, 41, 43, drawn to a polynucleotide of SEQ ID NO: 3, a vector and a host cell, classified in class 536, subclass 23.5.
- V. Claims 39, 41, 43, drawn to a polynucleotide of SEQ ID NO: 4, a vector and a host cell, classified in class 536, subclass 23.5.
- VI. Claims 40, 42, 44, drawn to a polynucleotide of SEQ ID NO: 7, a vector and a host cell, classified in class 536, subclass 23.5.
- VII. Claims 40, 42, 44, drawn to a polynucleotide of SEQ ID NO: 8, a vector and a host cell, classified in class 536, subclass 23.5.

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The inventions are distinct, each from the other because of the following reasons:

Inventions II-VII are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function, and each has an independent use, that is distinct for each invention which cannot be exchanged. Nucleic acids and host cells are distinct because their structures and modes of action are different, which require non-coextensive searches. Furthermore, the nucleic acids of Inventions IV-VII are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function, and each has an independent use, that is distinct for each invention which cannot be exchanged. In the instant case the nucleic acids have characteristic differences in their structure, as evidenced by the differing nucleic acid sequences.

In addition, the host cells of Inventions II-III are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function, and each has an independent use, that is distinct for each invention which cannot be exchanged. The host cells comprise proteins which differ in structure, for example the host cell of invention II comprises a first hybrid protein comprising a DNA binding domain and a second protein comprising an activation domain, while the host cell of Invention III comprises a first hybrid protein comprising an intracellular region of a voltage gated ion channel and a second protein comprising an amino terminal inactivation region of an ion channel protein.

Accordingly, these Inventions are distinct.

Inventions II and III are related as product and process of use to Invention I. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

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product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the host cells can be used in a method of producing the hybrid proteins.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are

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governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Joseph F. Murphy, Ph. D.

Patent Examiner Art Unit 1646 February 20, 2004